

INTERNATIONAL COOPERATION TREATY

PCT



4 DEC 2004

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCTA/KRIB/1	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/KR2003/001279	International filing date (day/month/year) 28 JUNE 2003 (28.06.2003)	Priority date (day/month/year) 29 JUNE 2002 (29.06.2002)
International Patent Classification (IPC) or national classification and IPC IPC7 C12N 15/31		
Applicant Korea Reaserch Institute of Bioscience and Biotechnology et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>4</u> sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of _____ sheets.
3.	This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 29 JANUARY 2004 (29.01.2004)	Date of completion of this report 11 OCTOBER 2004 (11.10.2004)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer CHANG, Je Hwan  Telephone No. 82-42-481-8158

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2003/001279

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION

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PCT/KR2003/001279

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-5, 7, 9-11, 13, 14	YES
	Claims	6, 8, 12	NO
Inventive step (IS)	Claims	1-5, 7, 9-11	YES
	Claims	13, 14	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims	none	NO

2. Citations and explanations (Rule 70.7)

The following document is cited in the International Search Report::

D1 : WO 98/01535 (Novo Nordisk A/S) 15 January 1998

Novelty :

Claim 6 of the present application relates to a *Hansenula polymorpha* mutant strain having reduced yapsin activity by mutation of *HpYPS1* gene encoding *Hansenula polymorpha* yapsin1.

Claim 8 relates to a recombinant *Hansenula polymorpha* strain expressing a foreign protein which is prepared by introducing gene encoding the foreign protein to the *Hansenula polymorpha* mutant strain according to claim 6.

D1 discloses a method for the production of polypeptide in yeast by culturing yeast having reduced activity of Yap3 (YPS1) which can be selected from the group comprising *Hansenula polymorpha* (see claims 1, 2, 5 and 35 of D1). Therefore, claims 6 and 8 are not novel because *Hansenula polymorpha* mutant strain having reduced YPS1 activity by mutation of gene encoding YPS1 for the production of foreign polypeptide is disclosed in D1 (PCT Article 33(2)).

Claim 12 relates to a process for preparing and isolating a foreign protein by expressing the foreign protein in the yapsin1 deficient *Hansenula polymorpha* strain according to claim 8.

D1 discloses the production of a foreign protein in yeast lacking Yap3 protease activity (see Claim 3 of D1). Therefore, claim 12 is not novel (PCT Article 33(2)).

(Continued to Supplemental Box)

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Box V

Inventive Step :

Claims 13 and 14 further define the protein in the process according to claim 12 as having a basic or dibasic amino acid residue which can be cleaved by yapsin1, preferably human PTH, human serum albumin or albumin fusion protein. However, the protein in claims 13 and 14 is arbitrarily selected and IPEA cannot find any particular technical features. Therefore, claims 13 and 14 are considered to lack an inventive step (PCT Article 33(3)).